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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,238	12/21/2001	Jayne E. Hastedt	0075.00	6678

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EXAMINER	
MERTZ, PREMA MARIA	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,238	HASTEDT ET AL.	
	Examiner	Art Unit	
	Prema M Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *41-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Applicants election with traverse of Group I (claims 1-40) on 2/12/2004 drawn to a spray dried powder composition comprising IL-4 receptor is acknowledged. The traversal is on the ground(s) that the restriction is improper since the examiner has not shown that examination of the methods of Groups II-III (claims 40-43) which relate to novel spray dried powders of IL-4R, would entail a serious burden. This argument is not found persuasive because the searches for the two Groups would not overlap, the inventions being classified in different classes and subclasses. Applicants are directed to MPEP 808.02 which states that "Where the related inventions as claimed are shown to be distinct and under the criteria of MPEP 806.05 (c-I), the examiner in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following: 1) Separate classification thereof." In the instant case, Group I is classified in class 424, subclass 46, Group II is classified in class 424, subclass 45, and Group III is classified in class 424, subclass 489.

The test for propriety of restriction is not whether the inventions are related but rather whether they are distinct and whether it would impose a burden on the examiner to search and examine multiple inventions in a single invention. The inventions of Groups II-III and Group I are related as process of making and product made, respectively. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP

§ 806.05(f)). In the instant case, the IL-4R powder can be prepared by a materially different process, such as lyophilization.

Lastly the inventions are distinct because a search of the literature a spray dried powder composition comprising IL-4R, would not necessarily be expected to reveal art for the other methods of obtaining the composition, which searches are extensive requiring separate searches which would be unduly burdensome.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has prima facie shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

The Groups as delineated in the restriction requirement of 1/21/2004 are patentably distinct one from the other such that each invention could, by itself, in principle, support its own separate patent (as shown by the arguments put forth in the written restriction requirement).

The requirement is still deemed proper and is therefore made FINAL.

Claims 41-43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112, second paragraph

2. Claims 1-40 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite for reciting "IL-4R" because the full meaning of the acronym "IL-4R" should be stated at its first use in any independent claim.

Claim 3 is improper because it recites "either claim 1". However, there is only a single claim 1.

Claims 3-4, lines 2-3, recite "spray dried solution or suspension" which is unclear because a powder composition is being claimed. Appropriate clarification is requested.

Regarding claims 4, 6-13, 15-20, 30-32, the phrase "characterized" renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 21 is vague and indefinite because it recites "aerosolized form". Does the recitation of this term mean a "pressurized can"? An acetone extract of blood in a spray bottle means the limitation of this claim. The metes and bounds of the claim are unclear.

Claim 22 is incorrect because "excipients" has been mis-spelled.

Claims 10-13 recite "insoluble aggregates" which is vague and indefinite because solubility depends on the aqueous media. Is the claimed powder in an aqueous solution? Clarification and appropriate correction with respect to this issue is requested.

Claim 14, line 1 is improper because it recites "claims 1".

Claims 30-32 are vague and indefinite because it is unclear what the "emitted dose" is and what the "emitted dose" is being compared to because there is no baseline for the "emitted dose" recited in the claims.

Claims 2, 5, 23-30, 37-40 are rejected as vague and indefinite insofar as they depend on the above rejected claims for their limitations.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-32, 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Nossal (1948)

Nossal teaches an acetone powder composition of whole blood as well as erythrocytes (see column 2, page 36, second para). Since IL-4 receptors are located on erythrocytes the whole blood powder as well as erythrocyte powder encompasses a powder composition comprising IL-4R. Therefore, the reference meets the requirements of the instant claims because of the "comprising" language".

With respect to claims 3-5, he reference does not explicitly recite the decrease in monomer content and extent of formation of aggregates as compared to the spray-dried solution. The burden is upon applicants to demonstrate that these limitations are absent from the acetone powder of the prior art. It is the Examiner's position that the reference does not explicitly state the presence of monomers the receptor and therefore the reference meets the requirements of the instant claims.

With respect to claims 6-9, which recite a decrease in monomer content, the prior art powder meets the limitations of these claims in the absence of such a showing, since the receptor in the acetone extract of the reference is the undissociated, intact receptor. Similarly, with respect to claims 15-20, which recite a decrease in monomer content, the prior art powder meets the limitations of these claims in the absence of such a showing,

since the receptor in the acetone extract of the reference is the undissociated, intact receptor.

With respect to claims 23, 28, which recites "at least one pharmaceutically acceptable excipient" the blood powder of the prior art comprises 2M acetate buffer (column 2, first para") which meets this limitation.

With respect to claim 24, which recites "amino acids" the blood powder of the prior art is an extract of blood and comprises amino acids which meets this limitation.

With respect to claim 25, which recites "sugar" the blood powder of the prior art is an extract of blood and comprises glucose which meets this limitation.

With respect to claim 26, which recites "hydrophobic amino acid" the blood powder of the prior art is an extract of blood and comprises hydrophobic amino acids like praline which meets this limitation.

With respect to claim 27, which recites "citric salts, leucine" the blood powder of the prior art is an extract of blood and comprises components of the citric acid cycle and amino acids leucine which meets this limitation.

With respect to claim 29, which recites "divalent cation" the blood powder of the prior art is an extract of blood and comprises divalent cations like Ca2++ and Mg2++, which meets this limitation.

Claims 38-39 recite that the "residual moisture content" of the powder is "less than about 10%" or "5% by weight". Since acetone extracts all of the water from protein molecules, it is the Examiner's position that the reference meets the requirements of the instant powder composition.

Claim 39 recites a range of "0.1-10 g/cc" which is a broad range for the bulk density of the powder composition. In the absence of showing otherwise, the acetone powder taught by the prior art reference meets the limitations of the instant claims.

Claim 40 recites "unit dosage form" but the claim does not specify a specific unit dosage form. Therefore, this limitation does not impart patentability to the claim and the reference meets the requirements of the instant powder composition.

Therefore, the acetone powder extract of the reference anticipates the instant claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6a. Claims 1-40 are rejected under 35 U.S.C. § 103 as being unpatentable over Mosley et al (US Patent No. 5,599,905) in view of Platz et al. (U.S. Patent No. 6,582,728).

Mosley et al. teaches that since IL-4 enhances secretion of IgE by stimulated B cells, the IL-4 receptor and soluble IL-4 receptor being useful in allergy therapy (see column 1, lines 24-36; column 3, lines 7-32). Mosley also teaches administration of the IL-4R by bolus injection and other suitable techniques (see column 16, lines 3-7), but does not teach the preparation of IL-4R as a powder form.

Platz et al. teaches the advantages of using powdered compositions for administration by inhalation and discloses that powdered compositions exhibit a high level of stability (see column 4, lines 39-57). Platz also teaches that these powdered drugs delivered to the lung are readily absorbed through the alveolar region directly into blood circulation (column 1, lines 25-40 and lines 64-67; column 2, lines 1-5). The reference teaches the dry powder has a moisture content of less than 10% and usually below 5% by weight (%w) water (column 5, lines 54-59) and an aerosol particle size distribution of 0.3 to 5 μm (MMAD) (column 5, lines 27-54). The reference also teaches pharmaceutical excipients such as amino acids, sugars and buffers, which are carriers of the powder (column 6, lines 65-68; column 7, lines 1-30).

Therefore, it would have been prima facie obvious to one having ordinary skill in the art to modify the IL-4R polypeptide composition of Mosley et al. such that it includes obtaining an IL-4R powder composition as taught by Platz et al., to obtain the known functions of powdered compositions as per the teachings of Platz et al. which teaches the advantages of delivering powders for pulmonary conditions. It would be obvious to obtain the IL-4R in powdered form to improve the therapeutic potential of IL-4R. One would have been motivated to obtain the IL-4R in powdered form because Platz teaches that the powdered form is free of liquid propellants such as CFC, HFC or carbon dioxide,

the powdered form can be easily manufactured and maintains a high percentage of pharmaceutical activity and exhibits a high level of stability (column 4, lines 39-57)

With respect to claims 3-9, 15-20, there would be a reasonable expectation of success for one of skill in the art to obtain the IL-4R in the active monomeric form.

Therefore, the prior art references render obvious the instant claims.

6b. Claims 1-40 are rejected under 35 U.S.C. § 103 as being unpatentable over Lange (1999) in view of Platz et al. (U.S. Patent No. 6,582,728).

Lange teaches that since soluble IL-4 receptor administration for treatment of asthma, said IL-4R being administered as a spray in solution form (page 526, see column 1, lines 1-3). Lange also teaches administration of the IL-4R in a single dose (page 526, see column 2, last 2 lines; page 527, column 1, first line), but does not teach the preparation of IL-4R as a powder form.

Platz et al. teaches the advantages of using powdered compositions for administration by inhalation and discloses that powdered compositions exhibit a high level of stability (see column 4, lines 39-57). Platz also teaches that these powdered drugs delivered to the lung are readily absorbed through the alveolar region directly into blood circulation (column 1, lines 25-40 and lines 64-67; column 2, lines 1-5). The reference teaches the dry powder has a moisture content of less than 10% and usually below 5% by weight (%w) water (column 5, lines 54-59) and an aerosol particle size distribution of 0.3 to 5 μm (MMAD) (column 5, lines 27-54). The reference also teaches pharmaceutical excipients such as amino acids, sugars and buffers, which are carriers of the powder (column 6, lines 65-68; column 7, lines 1-30).

Therefore, it would have been prima facie obvious to one having ordinary skill in the art to modify the IL-4R spray solution of Lange such that it includes obtaining an IL-4R powder composition as taught by Platz et al., to obtain the known functions of powdered compositions as per the teachings of Platz et al. which teaches the advantages of delivering powders for pulmonary conditions. It would be obvious to obtain the IL-4R in powdered form to improve the therapeutic potential of IL-4R. One would have been motivated to obtain the IL-4R in powdered form because Platz teaches that the powdered form is free of liquid propellants such as CFC, HFC or carbon dioxide, the powdered form can be easily manufactured and maintains a high percentage of pharmaceutical activity and exhibits a high level of stability (column 4, lines 39-57)

With respect to claims 3-9, 15-20, there would be a reasonable expectation of success for one of skill in the art to obtain the IL-4R in the active monomeric form.

Therefore, the prior art references render obvious the instant claims.

Conclusion

No claim is allowable.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 271-0871.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a

possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
March 1, 2004